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2000 U.S. App. LEXIS 8601, *

ROBERT S. **WASHBURN**, Plaintiff, LILLIAN E. AWAD, Plaintiff-Appellant, -v- MERCK & CO., INC., Defendant-Appellee.

No. 99-9121

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

2000 U.S. App. LEXIS 8601

May 1, 2000, Decided

NOTICE: [*1] RULES OF THE SECOND CIRCUIT COURT OF APPEALS MAY LIMIT CITATION TO UNPUBLISHED OPINIONS. PLEASE REFER TO THE RULES OF THE UNITED STATES COURT OF APPEALS FOR THIS CIRCUIT.

PRIOR HISTORY: Appeal from the United States District Court for the Southern District of New York (Stanton, J.).

DISPOSITION: AFFIRMED.

CASE SUMMARY

PROCEDURAL POSTURE: Plaintiff appealed the judgment of the United States District Court for the Southern District of New York, which granted summary judgment in favor of defendant in plaintiff's action claiming that as a result of receiving a certain rubella vaccine, she developed arthralgia, chronic arthropathy and chronic pain syndrome.

OVERVIEW: Plaintiff commenced an action against defendant, claiming that as a result of receiving the Meruvax II rubella vaccine, she developed arthralgia, chronic arthropathy and chronic pain syndrome. The district court granted summary judgment in favor of defendant holding that, pursuant to the Daubert standard, plaintiff's expert testimony was not admissible under Fed. R. Evid. 702 and 703, and therefore plaintiff could not have proven causation. On appeal, the court concluded that the district court did not abuse its discretion in determining that plaintiff's expert testimony was unreliable because it was based on little more than temporal correlation between plaintiff's vaccination and the onset of symptoms. Plaintiff's expert testimony did not appear to have been grounded in scientifically valid methodology or reasoning and thus was inadmissible under the Daubert standard. Plaintiff's ill-supported contention that defendant's epidemiological studies were flawed was rejected.

OUTCOME: Judgment affirmed; the district court properly applied the Daubert standard and did not abuse its discretion in excluding the testimony of plaintiff's experts, and absent admissible evidence of causation, defendant was entitled to summary judgment.

CORE TERMS: chronic, arthritis, symptoms, rubella vaccine, vaccination, expert testimony, rubella, pain, methodology, causation, causal relationship, vaccine, Vaccine Act, arthralgia, excluding, summary judgment, epidemiological, fibromyalgia, arthropathy, onset


EXHIBIT


B

scientifically, inadmissible, admissible, admissible evidence, temporal proximity, anecdotal, grounded, temporal, syndrome, swelling


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Civil Procedure > Summary Judgment

Civil Procedure > Appeals > Standards of Review > De Novo Review 


HN1  The appellate court reviews de novo the district court's grant of summary judgment. [More Like This Headnote](#)

Civil Procedure > Appeals > Standards of Review > Abuse of Discretion 

HN2  The district court's exclusion of expert testimony pursuant to the Daubert standard will be affirmed unless it constituted an abuse of discretion. [More Like This Headnote](#)

Evidence > Witnesses > Expert Testimony 

Criminal Law & Procedure > Evidence > Scientific Evidence > Daubert Standard 

HN3  Under the Daubert standard, expert testimony is admissible under Fed. R. Evid. 702 only if the trial court determines that it is both relevant and reliable. The trial court is charged with making a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue. In analyzing scientific validity, the trial court considers, among other things, (1) whether the expert's theory is capable of being tested; (2) whether the theory has been scrutinized by others in the field by means of peer review or publication; (3) the known or potential error rate associated with the underlying technique; (4) whether standards and controls have been used in testing; and (5) whether the technique and theory (not the conclusions) at issue are generally accepted in the particular scientific community. [More Like This Headnote](#)

COUNSEL: Appearing for Appellant: Anthony P. Gentile, Godosky & Gentile, P.C., New York, NY.

Appearing for Appellee: Richard L. Josephson, Baker Botts L.L.P., Houston, TX.

JUDGES: Present: ROSEMARY S. POOLER, SONIA SOTOMAYOR, * Circuit Judges.

* Judge Van Graafeiland, who was originally assigned as a member of the panel designated to hear this appeal, became ill shortly before the scheduled oral argument and was unable to participate in its argument or disposition. The remaining two members of the panel, who agree on the disposition, issue this order pursuant to 2d Cir. R. § 0.14(a), (b). See *Murray v. National Broadcasting Co., Inc.*, 35 F.3d 45, 47-48 (2d Cir. 1994).

OPINION: SUMMARY ORDER

ON CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the order of said District Court be and it hereby is **AFFIRMED**.

Lillian E. Awad appeals from an order of the [*2] United States District Court for the Southern District of New York (Stanton, J.) granting summary judgment in favor of defendant Merck & Co., Inc. ("Merck"). In 1989, Awad was a graduate student and worked at Albert Einstein Medical Center as a lab technician. Pursuant to New York law, Awad's employer routinely administered rubella (German measles) vaccinations to its female health care workers of child-bearing age. On July 6, 1989, Awad received Meruvax II, which is Merck's brand of Wistar Institute RA 27/3, a live virus vaccine against rubella. Subsequent to her

vaccination, Awad developed an acute illness, which included swelling of joints, rash and flu-like symptoms. Over the course of the next year, Awad continued to experience joint and muscle pain and her treating physicians diagnosed her with chronic arthropathy, chronic pain syndrome, and fibromyalgia.

Awad commenced this action against Merck in October 1995, claiming that as a result of receiving the Meruvax II rubella vaccine, she developed arthralgia, chronic arthropathy and chronic pain syndrome. Merck moved for summary judgment, claiming that Awad's evidence of causation was inadmissible under the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993). In addition, Merck claimed that plaintiff's claims were barred under the National Childhood Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-1, et seq. ("Vaccine Act"). The district court granted summary judgment in favor of Merck holding that, pursuant to *Daubert*, plaintiff's expert testimony was not admissible under Fed. R. Evid. 702 and 703, and therefore plaintiff could not prove causation. The district court did not address the Vaccine Act claim. On appeal, Awad argues that the district court abused its discretion in excluding her causation testimony and exceeded its gatekeeping role by determining an issue which should have been decided at trial. For the reasons below, we reject appellant's arguments and affirm the judgement of the district court.

HN1 We review de novo the district court's grant of summary judgment. See *Wilkinson v. Russell*, 182 F.3d 89, 96 (2d Cir. 1999). **HN2** The district court's exclusion of expert testimony pursuant to *Daubert v. Merrell Dow* will be affirmed unless it constituted **[*4]** an abuse of discretion. See *General Elec. Co. v. Joiner*, 522 U.S. 136, 142, 139 L. Ed. 2d 508, 118 S. Ct. 512 (1997). **HN3** Under *Daubert*, expert testimony is admissible under Rules 702 of the Federal Rules of Evidence only if the trial court determines that it is both relevant and reliable. See *Daubert*, 509 U.S. at 589-90. The trial court is charged with making a "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93. In analyzing scientific validity, the trial court considers, among other things, 1) whether the expert's theory is capable of being tested; 2) whether the theory has been scrutinized by others in the field by means of peer review or publication; 3) the known or potential error rate associated with the underlying technique; 4) whether standards and controls have been used in testing; and 5) whether the technique and theory (not the conclusions) at issue are generally accepted in the particular scientific community. *Id.* at 593-94.

In this **[*5]** case, the district court rejected the testimony of Doctors Lans, Dorsch and Wetherbee on the issue of causation and concluded that their opinions were based largely on the temporal proximity of the vaccination to the onset of Awad's symptoms and were not grounded in the methods of science. Appellant contends that while there is genuine disagreement in the medical research community as to whether there is a link between the rubella vaccine and the development of chronic joint pain and the symptoms associated with her illness, she nevertheless offered admissible evidence as to causation. For example, appellant argues that Judge Stanton improperly dismissed a 1979 study by Aubrey Tingle in which several women showed evidence of acute and chronic arthritis and arthralgia conditions merely because it studied a small population and only two of the subjects actually received RA 27/3, as opposed to its predecessor vaccine. In response, Merck acknowledges that during the 1980s, several researchers hypothesized that there could be a link between rubella vaccines and chronic arthritis. As Merck points out, Awad does not complain of arthritis, which is characterized by objectively observable **[*6]** swelling of the joints, but rather arthropathy, arthralgia and chronic fibromyalgia, which are characterized by more subjective symptoms. Furthermore, the evidence linking the vaccine with arthritis is derived mainly from anecdotal reports and small population studies with few controls. Merck also argues that while an Institute of Medicine Report in 1991 suggested a connection between

rubella vaccine and chronic arthritis, and suggested ways in which such a study could be conducted, it noted, significantly, that such a "relation between rubella vaccine and chronic arthritis remains unproved." Since that report, three large, controlled epidemiological studies found no evidence of a causal relationship between immunization with RA27/3 rubella vaccine and persistent joint symptoms or other chronic joint disease conditions. In addition, one study that specifically examined the association between Meruvax II and fibromyalgia found no causal relationship between the two.

We conclude that the district court did not abuse its discretion in determining that plaintiff's expert testimony was unreliable because it was based on little more than temporal correlation between Awad's vaccination and [*7] the onset of symptoms. See *Cavallo v. Star Enterprise*, 892 F. Supp. 756 (E.D. Va. 1995), *aff'd* in relevant part, 100 F.3d 1150 (4th Cir. 1996); *Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972, 1023 (S.D. Ohio 1992), *aff'd* 24 F.3d 809 (6th Cir. 1994). Dr. Dorsch provided only conclusory statements that Awad had "polyarthralgias, most likely resulting from Rubella vaccine." Taking into account an array of factors consistent with Daubert, Judge Stanton properly rejected Dorsch's conclusion that Awad's joint condition was related to the rubella vaccine because it was supported by nothing more than temporal proximity. Similarly, it was well within the discretion of the district court to exclude the unsubstantiated opinion of Dr. Lans that Awad's condition was the result of vaccination. Nor are we persuaded that the district court erred in excluding the testimony of Dr. Wetherbee. Based on his review of Awad's medical records, studies linking the rubella virus with chronic arthritis, and the temporal relationship between vaccination and onset of symptoms, Wetherbee opined that appellant's chronic joint pain resulted from Meruvax [*8] II. The district court emphasized that Wetherbee's opinion did not emanate from his own research in the field, but rather was developed for purposes of litigation. Judge Stanton reviewed the articles on which Wetherbee based his opinion and evaluated the validity of the methodology under Daubert. Judge Stanton reviewed the studies and articles that Wetherbee used to conclude that there is a causal relationship between RA 27/3 and chronic joint conditions and found that none was a large-scale epidemiological study and most were either anecdotal, or did not involve RA 27/3. We conclude that it was well within Judge Stanton's discretion to exclude Wetherbee's testimony. Plaintiff's expert testimony does not appear to be grounded in scientifically valid methodology or reasoning and thus is inadmissible under Daubert. Finally, we reject appellant's ill-supported contention that Merck's epidemiological studies (which show no causal relationship between RA 27/3 and chronic joint problems) are flawed.

We conclude that the district court properly applied the Daubert standard and did not abuse its discretion in excluding the testimony of plaintiff's experts. Absent admissible evidence [*9] of causation, Merck was entitled to summary judgment. There is no need for us to consider the parties' arguments related to the Vaccine Act. Accordingly, we affirm the judgment of the district court.

We have examined all of the appellant's contentions and find them to be without merit.

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Service: **Get by LEXSEE®**
Citation: **1996 us app lexis 22329**

*1996 U.S. App. LEXIS 22329, **

BENJAMIN AUSTIN; VICKIE AUSTIN, Co-Administrators of the Estate of Zachary Allen Austin, deceased, Plaintiffs-Appellants, v. CHILDREN'S HOSPITAL MEDICAL CENTER; SUSAN HALL, Defendants-Appellees, XAVIER UNIVERSITY, Defendant.

No. 95-3880

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

1996 U.S. App. LEXIS 22329

July 26, 1996, FILED

NOTICE: [*1] NOT RECOMMENDED FOR FULL-TEXT PUBLICATION. SIXTH CIRCUIT RULE 24 LIMITS CITATION TO SPECIFIC SITUATIONS. PLEASE SEE RULE 24 BEFORE CITING IN A PROCEEDING IN A COURT IN THE SIXTH CIRCUIT. IF CITED, A COPY MUST BE SERVED ON OTHER PARTIES AND THE COURT. THIS NOTICE IS TO BE PROMINENTLY DISPLAYED IF THIS DECISION IS REPRODUCED.

SUBSEQUENT HISTORY: Reported in Table Case Format at: 92 F.3d 1185, 1996 U.S. App. LEXIS 25803.

PRIOR HISTORY: ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO.

DISPOSITION: AFFIRMED.

CASE SUMMARY

PROCEDURAL POSTURE: In a medical malpractice action, appellant parents sought review of a decision from the United States District Court for the Southern District of Ohio, which granted appellee hospital's motion for summary judgment.

OVERVIEW: The parents gave consent to the hospital for a bone marrow transplant for their son. The child later died of a viral infection, and the parents contended that the infection was caused by an infected nurse who entered the son's room without a mask. The parents filed a malpractice action against the hospital, and the hospital filed a motion for summary judgment. The court granted the motion, and the parents sought review. The court affirmed. It found that the parents failed to create a triable issue of fact on the issue of causation because the opinion of the parents' expert witness was conclusory and insufficient to allow a reasonable jury to conclude that their position was more likely than not true.


OUTCOME: The court affirmed the grant of summary judgment rendered in favor of the hospital.


CORE TERMS: adenovirus, summary judgment, infection, decedent, causation, standard of care, adenoviruses, serotype, symptoms, issue of causation, expert witness, transplant, diversity, exposure, antibody, exposed, viral, mask


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EXHIBIT


C

Civil Procedure > Summary Judgment > Summary Judgment Standard 


Civil Procedure > Appeals > Standards of Review > De Novo Review 


HN1  The court reviews a grant of summary judgment de novo, applying the same test as the district court. Summary judgment is proper if the record, when viewed in the light most favorable to the nonmoving party, reveals that there are no genuine issues of material fact in dispute and that the moving party is entitled to judgment as a matter of law. [More Like This Headnote](#)

Torts > Malpractice Liability > Healthcare Providers 

HN2  To establish medical malpractice under Ohio law, the plaintiff must establish: (1) the existence of a standard of care within the medical community; (2) a breach of the standard of care by the defendant; (3) injury; and (4) direct and proximate causation. [More Like This Headnote](#)

Civil Procedure > Summary Judgment > Supporting Papers & Affidavits 

Civil Procedure > Summary Judgment > Burdens of Production & Proof 

HN3  A plaintiff may not escape summary judgment merely by producing an expert witness. If a court concludes that the evidence supporting the expert's position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, then the court remains free to prohibit the case from proceeding to the jury. Although courts should be careful to respect scientific opinion, nevertheless courts apply a hard look to the reasoning of qualified scientific opinions to determine whether a triable issue has been created. Of course, an expert opinion which is conclusory and fails to set forth the underlying rationale is not adequate. [More Like This Headnote](#)

COUNSEL: For BENJAMIN AUSTIN, Plaintiff - Appellant: David P. Kamp, Patricia C. Wason, White, Getgey & Meyer, Cincinnati, OH.

For VICKIE AUSTIN, Co-Administrators of the Estate of Zachary Allen Austin, deceased, Plaintiff - Appellant: David P. Kamp, (See above). Patricia C. Wason, (See above).

For CHILDREN'S HOSPITAL MEDICAL CENTER, Defendant - Appellee: James A. Comodeca, Frank C. Woodside, III, Dinsmore & Shohl, Cincinnati, OH.

For SUSAN HALL, Defendant - Appellee: Mark E. Elsener, Mark G. Whittenburg, Porter, Wright, Morris & Arthur, Cincinnati, OH.

JUDGES: BEFORE: MERRITT, Chief Judge; BROWN and SUHRHEINRICH, Circuit Judges.

OPINION: PER CURIAM. In this diversity action, plaintiffs Benjamin and Vickie Austin allege that Children's Hospital Medical Center [*2] ("CHMC") and Susan Hall negligently exposed plaintiffs' son Zachary to a viral infection which resulted in Zachary's death. Plaintiffs appeal from the grant of summary judgment dismissing their cause of action. We conclude that plaintiffs failed to create a triable issue of fact on the issue of causation and **AFFIRM** the dismissal.

BACKGROUND

Zachary Austin was born on November 11, 1990, in Alabama. Shortly after birth, Zachary was diagnosed with beta thalassemia major, a blood disorder which inhibits the production of red blood cells. The Austins elected to have Zachary undergo a bone marrow transplant at CHMC in Cincinnati. Zachary was admitted to CHMC on February 12, 1992, and the

transplant was performed on February 28, 1992.

After the procedure, Zachary was placed in an isolation room. On March 10, 1992, Susan Hall, a student nurse from Xavier University, entered Zachary's room wearing a mask. Hall indicated at the time that she had a scratchy throat. Later that same day, Hall reentered Zachary's room to attend to Zachary, this time without a mask. Hall went home early that day with a fever.

Zachary subsequently developed signs of an infection. Cultures taken on [*3] March 13, 1992, tested positive for adenovirus. Zachary was treated for his adenovirus infection and discharged from CHMC. After traveling to his home in Alabama, Zachary had to be rehospitalized. Zachary died of a viral infection on May 17, 1992.

Plaintiffs, residents of Alabama, filed this action in federal district court in May 1993 alleging wrongful death under Ohio law. The initial named defendants were CHMC, Susan Hall, and Xavier University; plaintiffs subsequently settled with Xavier University. Diversity jurisdiction was proper pursuant to 28 U.S.C. § 1332. Defendants moved for summary judgment. Plaintiffs opposed, submitting the affidavit of Dr. Raff, a board certified physician in infectious diseases and Chief of the Section of Infectious Diseases at the University of Louisville School of Medicine. The district court granted summary judgment on the grounds that plaintiffs had failed to establish the cause or source of Zachary's infection. Plaintiffs timely appealed.

ANALYSIS

HN1 We review the grant of summary judgment de novo, applying the same test as the district court. *Ayoub v. National R.R. Passenger Corp.*, 76 F.3d 794, 795 (6th Cir. 1996). Summary judgment [*4] is proper if the record, when viewed in the light most favorable to the nonmoving party, reveals that there are no genuine issues of material fact in dispute and that the moving party is entitled to judgment as a matter of law. *Maldonado v. National Acme Co.*, 73 F.3d 642, 644 (6th Cir. 1996).

HN2 To establish medical malpractice under Ohio law, the plaintiff must establish: (1) the existence of a standard of care within the medical community; (2) a breach of the standard of care by the defendant; (3) injury; and (4) direct and proximate causation. *Littleton v. Good Samaritan Hosp. & Health Ctr.*, 39 Ohio St. 3d 86, 529 N.E.2d 449 (Ohio 1988).

In the case at bar, plaintiffs introduced the affidavit of their expert witness, Dr. Raff, to establish the necessary elements of their wrongful death claim. Dr. Raff's affidavit on the issue of causation may be summarized as follows. Decedent tested negative for adenovirus antibodies indicating that he had not been exposed to adenovirus as of February 5, 1992. Decedent was shedding adenovirus and was febrile within three days of exposure to Susan Hall, the only person with symptomatic illness known to have been in contact with decedent. [*5] Based upon his education, training and experience, and his review of the record, Dr. Raff concluded that it was probable that decedent contracted the adenovirus from Susan Hall on March 10, 1992. Plaintiffs assert that Dr. Raff's affidavit creates a material issue of fact with respect to causation.

HN3 A plaintiff may not escape summary judgment merely by producing an expert witness. "If a court concludes that the evidence supporting the expert's position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, then the court remains free to prohibit the case from proceeding to the jury." *Glaser v. Thompson Medical Co.*, 32 F.3d 969, 972 (6th Cir. 1994) (citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 2798, 125 L. Ed. 2d 469 (1993)). Although courts should be careful to respect scientific opinion, nevertheless courts apply a "hard look" to the reasoning of qualified scientific opinions to determine whether a triable issue has been created. *Turpin*

v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349, 1252-53 (6th Cir.) (cited with approval in Daubert, 113 S. Ct. at 2798), cert. denied, [***6**] 506 U.S. 826, 121 L. Ed. 2d 47, 113 S. Ct. 84 (1992); Glaser, 32 F.3d at 972. Of course, an expert opinion which is conclusory and fails to set forth the underlying rationale is not adequate. Turpin, 959 F.2d at 1360.

Dr. Raff's affidavit suffers from numerous flaws. First, Dr. Raff states only that Hall's symptoms were "consistent" with an adenovirus. He fails to identify the basis for his subsequent conclusion that Hall in fact had adenovirus and not another ailment such as a fungal or bacterial infection. See *Conde v. Velsicol Chem. Corp.*, 24 F.3d 809, 814 (6th Cir. 1994) (holding insufficient showing of causation where testimony stated only that the symptoms were consistent with chlordane exposure without excluding other possible causes). Further, defendants introduced evidence that there are forty-two different recognized serotypes of adenoviruses, and that adenoviruses are ubiquitous and may be carried by individuals who are asymptomatic. Dr. Raff does not give his reasons for concluding that Zachary had the same serotype of adenovirus that Hall allegedly had, nor does he explain why he excluded the myriad of other potential sources of the adenovirus which infected [***7**] Zachary. Cf. *Glaser*, 32 F.3d at 977-78 (holding expert testimony sufficient where expert engaged in differential diagnosis to reach his conclusion).

Indeed, the only identifiable reason for Dr. Raff's opinion appears to be post hoc, ergo propter hoc. This alone is not sufficient to create a material issue of causation. *Abbott v. Federal Forge, Inc.*, 912 F.2d 867, 875 (6th Cir. 1990); *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817, 83 L. Ed. 2d 31, 105 S. Ct. 84 (1984).

We do not doubt that it is possible for Hall to have been the one to infect Zachary. Without evidence that this was more likely than not the case, however, the mere possibility of infection is not sufficient to avoid summary judgment. *Hasler*, 718 F.2d at 205 ("While an antibody antigen reaction can cause rheumatoid arthritis, there is no showing that it did cause the plaintiff's disease in this case.").

CONCLUSION

The grant of summary judgment dismissing plaintiffs' wrongful death suit is **AFFIRMED**.

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Citation: **2002 U.S. App. LEXIS 382**

*26 Fed. Appx. 472, *; 2002 U.S. App. LEXIS 382, ***

ANDREW A. DOWNS and MARIA DOWNS, Plaintiffs-Appellants, v. PERSTORP COMPONENTS, INC., and ICI AMERICAS, INC., Defendants-Appellees.

No. 00-5507

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

26 Fed. Appx. 472; 2002 U.S. App. LEXIS 382

January 4, 2002, Filed

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PRIOR HISTORY: ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TENNESSEE. 96-00597. Jarvis. 02-09-00, 03-15-00.

Downs v. Perstorp Components, 2000 U.S. Dist. LEXIS 20281 (E.D. Tenn. Mar. 15, 2000)

DISPOSITION: Affirmed.

CASE SUMMARY

PROCEDURAL POSTURE: Appellants, injured individual and his spouse (injured individual), challenged the decision of the United States District for the Eastern District of Tennessee, which granted summary judgment to appellee companies.

OVERVIEW: The injured individual brought an action against the companies for injuries allegedly suffered by him as a result of an exposure to a chemical product manufactured by one of the companies. The court affirmed the district court's grant of summary judgment to the companies. The court determined that the magistrate judge did not abuse his discretion in excluding the expert witness' testimony because his conclusions were not based on valid scientific methodology. The court explained that the expert witness testified that he found no scientific literature suggesting that the chemical product could lead to neurological problems, and had not conducted any testing to determine the potential effects of exposure to the chemical product or its components. The court noted that the expert witness never identified the component or components in the chemical product that were responsible for the injured individual's condition. The court concluded that the district court correctly held that, without admissible expert testimony on causation, no reasonable jury could find for the injured individual because Tennessee law required proof of causation for both strict liability and negligence actions.

OUTCOME: The court affirmed the district court's orders excluding the testimony of the expert witness, denying the injured individual's request for relief from the terms of the agreed order, and granting summary judgment for the companies.


CORE TERMS: methodology, scientific, exposure, summary judgment, agreed order


EXHIBIT


D


causation, issue of causation, neurological, container, chemical, dose, scientific literature, conducting, hypothesis, diagnosed, testing, exposed, strict liability, expert testimony, expert-witness, admissibility, reliability, validation, disclosure, assessing, evidence of causation, methodological, independently, constituent, repackaging


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Civil Procedure > Appeals > Standards of Review > De Novo Review 

Civil Procedure > Appeals > Standards of Review > Abuse of Discretion 


HN1  The court reviews the district court's decision to exclude the testimony of plaintiffs' expert witnesses for abuse of discretion. The court reviews the district court's grant of summary judgment de novo. [More Like This Headnote](#)


Evidence > Witnesses > Expert Testimony 

Criminal Law & Procedure > Evidence > Scientific Evidence > Daubert Standard 


HN2  The United States Supreme Court (Court) holds that the Federal Rules of Evidence provide the standard for admitting expert scientific testimony and require that such testimony must be both relevant and reliable. The Court explains that in order to qualify as "scientific knowledge," an inference or assertion must be derived from the scientific method. Proposed testimony must be supported by appropriate validation--for example, "good grounds," based on what is known. In assessing the admissibility of expert scientific testimony, the trial judge must conduct a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue. The Court identifies several factors that may be included in this inquiry but emphasized that the inquiry is "a flexible one." These factors include whether the theory or technique can be and has been tested, has been subject to peer review and publication, has a known potential error rate, and is generally accepted by the scientific community. [More Like This Headnote](#)

Evidence > Witnesses > Expert Testimony 


HN3  It is implausible to suggest that parties will present less than their best expert evidence in the expectation of a second chance should their first try fail. [More Like This Headnote](#)


Evidence > Witnesses > Expert Testimony 

Governments > Courts > Authority to Adjudicate 

HN4  District courts have broad discretion to exclude untimely disclosed expert-witness testimony. [More Like This Headnote](#)

Torts > Products Liability > Strict Liability 

Torts > Negligence > Negligence Generally 

HN5  Tennessee law requires proof of causation for both strict liability and negligence actions. [More Like This Headnote](#)

COUNSEL: For ANDREW A. DOWNS, MARIA DOWNS, Plaintiffs - Appellants: Carl R. Ogle, Jr., Jefferson City, TN.

For PERSTORP COMPONENTS INC., Defendant - Appellee: Linda J. Hamilton Mowles, Harry P. Ogden, Lewis, King, Krieg, Waldrop & Catron, Knoxville, TN.

For ICI AMERICAS INC, Defendant - Appellee: Stephen E. Embry, Frost, Brown & Todd,

Louisville, KY.

For ICI AMERICAS INC, Defendant - Appellee: John W. Hays, Frost, Brown & Todd, Lexington, KY.

For ICI AMERICAS INC, Defendant - Appellee: J. Randolph Bibb, Jr., Baker, Donelson, Bearman & Caldwell, Nashville, TN.

JUDGES: BEFORE: NORRIS and BATCHELDER, Circuit Judges; GWIN, District Judge. *

* The Honorable James S. Gwin, United States District Judge for the Northern District of Ohio, sitting by designation. **[**2]**

OPINIONBY: ALAN E. NORRIS

OPINION: [*473] ALAN E. NORRIS, Circuit Judge. Andrew A. Downs and Maria Downs brought suit against defendants. Perstorp Components, Inc., ("Perstorp") and ICI Americas, Inc., ("ICI") for injuries allegedly suffered by Andrew Downs as a result of an exposure to Rubiflex SI 30690, a chemical product manufactured by ICI. The district court granted summary judgment to defendants. We affirm.

I.

In 1995, Perstorp purchased Rubiflex, which is used in the production of foam insulation, from ICI. Another company, SurfAir, was hired to transport the Rubiflex to Perstorp's operation in Tennessee. Downs reported that the plane chartered to ship the containers of Rubiflex was too small. JoAnn Holland, a SurfAir employee, then contacted Jayne Collyar, a Perstorp representative, about the problem. Collyar suggested repackaging the Rubiflex in smaller containers. Holland relayed this suggestion to Downs, who expressed some concern about breaking the seal on the container because he was afraid its contents might be hazardous. Holland told Downs that Rubiflex was not referenced in a book she had consulted on hazardous materials, and Downs proceeded to repackage the Rubiflex. **[**3]**

[*474] During the repackaging attempt, Rubiflex splashed out of the containers and onto Downs' arms and face. He experienced a burning sensation on his skin and contacted Holland to report the problem. After checking with Collyar, Holland assured Downs that exposure to the chemical was safe.

In December of 1995, Downs began noticing neurological symptoms and subsequently sought treatment from Dr. Kaye H. Kilburn. Dr. Kilburn diagnosed plaintiff with "chemical encephalopathy" and, after extensive testing, concluded that the cause of his condition was the exposure to Rubiflex.

In June 1996, plaintiffs instituted this diversity action. The complaint sought recovery against ICI based upon the Tennessee Product Liability Act and against Perstorp because one of its representatives negligently misrepresented the danger associated with exposure to Rubiflex.

The district court entered a discovery order requiring parties to submit expert-witness reports and disclosures required by Federal Rule of Civil Procedure 26(a)(2) by a certain date. n1 When plaintiffs failed to submit the required Rule 26(a) reports for Dr. Kilburn and another identified expert, Thomas J. Callender, M.D., by June of 1998, **[**4]** defendants moved to compel production of the reports. Plaintiffs ultimately produced Dr. Kilburn's report but failed to submit a report from Dr. Callender.

- - - - - Footnotes - - - - -

n1 Rule 26(a)(2)(B) requires that the disclosure of the identity of "a witness who is retained or specially employed to provide expert witness testimony in the case . . . be accompanied by a written report prepared and signed by the witness." FED. R. CIV. P. 26(a)(2)(B).

- - - - - End Footnotes - - - - -

After defendants moved to exclude any testimony by expert witnesses for whom plaintiffs had not produced a report, the parties agreed to an order stipulating that Dr. Callender would not offer testimony on causation. With respect to Dr. Kilburn, defendants moved to exclude his testimony on the ground that it failed to satisfy the standards for scientific testimony outlined in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993). The magistrate judge conducted a *Daubert* hearing and granted defendants' request to exclude Dr. **[**5]** Kilburn's testimony. The district court affirmed the exclusion of Dr. Kilburn's testimony.

At this point, defendants moved for summary judgment on the ground that plaintiffs lacked evidence of causation. In response, plaintiffs argued that they should be relieved of the restrictions placed on Dr. Callender's testimony by the earlier agreed order so that he could testify on the issue of causation. The district court concluded that plaintiffs were bound by the agreed order, and that, without the testimony of doctors Kilburn or Callender, plaintiffs lacked any evidence of causation. Accordingly, the court granted summary judgment to defendants.

II.

HN1 We review the district court's decision to exclude the testimony of plaintiffs' expert witnesses for abuse of discretion. *See Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 248 (6th Cir. 2001). We review the district court's grant of summary judgment de novo. *See Smith v. Ameritech*, 129 F.3d 857, 863 (6th Cir. 1997).

A. Exclusion of Dr. Kilburn's Testimony

Plaintiffs argue that Dr. Kilburn's testimony meets the standard of Federal Rule of Evidence 702 for the admission of expert testimony, **[**6]** as well as the criteria articulated by the Supreme Court in *Daubert* **[*475]** for assessing the admissibility of scientific evidence under Rule 702.

1. *Daubert* Standard

In *Daubert*, **HN2** the Supreme Court held that the Federal Rules of Evidence provide the standard for admitting expert scientific testimony and require that such testimony must be both relevant and reliable. *Daubert*, 509 U.S. at 589. The Court explained that "in order to qualify as 'scientific knowledge,' an inference or assertion must be derived from the scientific method. Proposed testimony must be supported by appropriate validation--i.e., 'good grounds,' based on what is known." *Id.* at 590. In assessing the admissibility of expert scientific testimony, the trial judge must conduct "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93. In *Daubert* the Court identified several factors that may be included in this inquiry but emphasized that the inquiry is "a flexible one." *Id.* at 594. **[**7]** These factors include whether the theory or technique can be and has been tested, has been subject to peer review and publication, has a known potential error rate, and is generally accepted by the scientific community. *Id.* at 593-94.

After careful review of the magistrate judge's opinion and the arguments made by the parties, we are convinced that the magistrate judge did not abuse his discretion in excluding Dr. Kilburn's testimony because his conclusions were not based on valid scientific methodology.

2. Dr. Kilburn's Methodology

The magistrate judge identified numerous "red flags" raised by Dr. Kilburn's proposed testimony. Among those that the magistrate judge identified were: (1) Dr. Kilburn's methodology is not accepted by the medical community; (2) he extrapolated results from unrelated chemical compounds in forming his conclusions; (3) he failed to test his hypothesis; and (4) he reached a conclusion before conducting any research.

In addition, the magistrate judge discussed problems with Dr. Kilburn's methodology in light of testimony by defendants' expert witnesses who described commonly accepted methods for conducting a toxicological investigation. **[**8]** The magistrate judge highlighted the fact that, at the time he diagnosed Andrew Downs, Dr. Kilburn was not aware of the constituent components of Rubiflex n2 and did not know the amount of Rubiflex to which Downs had been exposed. The magistrate judge also noted that Dr. Kilburn testified that he had found no scientific literature suggesting that Rubiflex could lead to neurological problems and had not conducted any testing himself to determine the potential effects of exposure to Rubiflex or its components. We agree that these represent fundamental flaws in the methodology underlying Dr. Kilburn's opinion that Rubiflex caused Downs' neurological problems.

----- Footnotes -----

n2 Dr. Kilburn did eventually familiarize himself with the constituent components of Rubiflex. His original conclusion, however, was based simply on Downs' symptoms and the fact that he had been exposed to Rubiflex.

----- End Footnotes -----

The most obvious problem with Dr. Kilburn's methodology is that he never identified the component or components in Rubiflex that were responsible **[**9]** for Downs' condition. Plaintiffs argue that it was sufficient that Dr. Kilburn identified Rubiflex as an epoxy and determined that it contains **[*476]** two substances identified as toxic in scientific literature. In his testimony, however, Dr. Kilburn admitted that he could not identify which components of Rubiflex caused the various neurological problems that he had diagnosed Downs as having, and that it would be simply speculation to attempt to identify the specific effects of these toxins. Moreover, Dr. Kilburn stated that his primary basis for concluding that Rubiflex is toxic was his observation of Downs' condition.

Another significant flaw in Dr. Kilburn's method was the fact that he made no attempt either to determine the dose to which Downs was exposed or to identify independently what dose of Rubiflex, or the toxins he had identified in Rubiflex, is necessary to cause the conditions that he observed in Downs. Therefore, Dr. Kilburn was unable to state whether Downs had received a dose sufficient for Rubiflex to have caused his condition and was unable to state what minimum dose would be required to do so.

In essence, Dr. Kilburn's methodology primarily involved reasoning backwards **[**10]** from Downs' condition and, through a process of elimination, concluding that Rubiflex must have caused it. Dr. Kilburn's response to the question of whether he had conducted any testing to calculate Downs' potential exposure summarizes his methodological approach: "We know we had an effect, we know that Rubiflex was there, we've excluded all other possibilities. . . . I

see nothing else needed."

As evidenced by the fact that he was unaware of the components of Rubiflex when he came to his initial conclusion about what caused Downs' condition, Dr. Kilburn's method does not include any reference to existing scientific knowledge or any attempt to test independently the validity of his conclusion. In effect, Dr. Kilburn simply formed a hypothesis based on his observations of Downs and what he knew of Downs' medical history. He failed to take the necessary step of either supporting his hypothesis through reference to existing scientific literature or conducting his own tests to prove its reliability. See *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (stating that "*Daubert* and its progeny make clear that 'proposed [expert] testimony must be supported by appropriate **[**11]** validation.'") (quoting *Daubert*, 509 U.S. at 591). In light of these methodological shortcomings, the magistrate judge did not abuse his discretion in determining that Dr. Kilburn's testimony should be excluded because it lacked scientific reliability.

B. Exclusion of Dr. Callender's Testimony

Plaintiffs argue that they should be relieved of the limitations in the agreed order that prohibited Dr. Callender from testifying on the issue of causation because, at the time it was entered, Dr. Kilburn's testimony had not yet been challenged. They contend that they agreed to limit Dr. Callender's testimony only because they assumed Dr. Kilburn would be permitted to testify on the issue of causation.

Plaintiffs' position is undermined by the fact that they were on notice of the potential exclusion of Dr. Kilburn's testimony for nearly fifteen months before they requested relief from the order. As the Supreme Court recently observed, ^{HN3} "It is implausible to suggest, post-*Daubert*, that parties will present less than their best expert evidence in the expectation of a second chance should their first try fail." *Weisman v. Marley Co.*, 528 U.S. 440, 442, 120 S. Ct. 1011, 145 L. Ed. 2d 958 (2000). **[**12]**

^{HN4} "District courts have broad discretion to exclude untimely disclosed expert-witness testimony." *Pride*, 218 F.3d at 578. In **[*477]** this case, the district court refused to grant the plaintiffs relief from an agreed order prohibiting Dr. Callender from testifying on the issue of causation because, at the time they agreed to this limitation, plaintiffs faced the very real threat that the magistrate judge would exclude Dr. Callender's testimony altogether due to their failure to produce an expert witness report. In view of that reasoning, we are unable to say that the district judge abused his discretion in refusing to relieve plaintiffs of the terms of their agreement.

C. Summary Judgment

The district court correctly concluded that, without admissible expert testimony on causation, no reasonable jury could find for plaintiffs because ^{HN5} Tennessee law requires proof of causation for both strict liability and negligence actions. See, e.g., *Caldwell v. Ford Motor Co.*, 619 S.W.2d 534, 539 (Tenn. Ct. App. 1981) (Tennessee strict liability statute requires a showing that the product caused the injury); *Dillard v. Vanderbilt Univ.*, 970 S.W.2d 958, 960 (Tenn. Ct. App. 1998) **[**13]** (negligence claim requires establishing causation in fact).

III.

The district court's orders excluding the testimony of Dr. Kilburn, denying plaintiffs' request for relief from the terms of the agreed order, and granting summary judgment for defendants are **affirmed**.

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Citation: 2001 us app lexis 16148

14 Fed. Appx. 559, *; 2001 U.S. App. LEXIS 16148, **

DARLENE WHEELER and JAMES WHEELER, Plaintiffs-Appellants, v. BAPTIST HEALTHCARE SYSTEM, INC. d/b/a WESTERN BAPTIST HOSPITAL, Defendant-Appellee.

No. 00-5518

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

14 Fed. Appx. 559; 2001 U.S. App. LEXIS 16148

July 16, 2001, Filed

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PRIOR HISTORY: ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF KENTUCKY. 98-00303. Russell. 03-20-00.

DISPOSITION: District court's grant of summary judgment in favor of Baptist Healthcare AFFIRMED. District court's denial of the Wheelers' motion to vacate AFFIRMED.

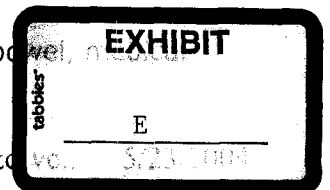
CASE SUMMARY

PROCEDURAL POSTURE: Plaintiffs, former patient and her husband, filed a medical malpractice complaint against defendant hospital alleging negligence, gross negligence, and loss of consortium. The United States District Court for the Western District of Kentucky granted the hospital's summary judgment motion. Plaintiffs moved to vacate the order. The district court denied the motion. Plaintiffs appealed.

OVERVIEW: The district court found that plaintiffs had not presented the necessary expert evidence that the hospital was negligent or that any negligence caused her medical problems. The general rule in Kentucky was that medical malpractice must have been established by medical or expert testimony unless the negligence and injurious results were so apparent that laymen would have had no difficulty in recognizing it. Plaintiffs claimed that the hospital was negligent in not following doctor's orders to give her an enema and that no expert testimony was necessary to illustrate the negligence involved. Plaintiffs presented no evidence to counter the hospital's expert affidavit that the physician's orders for the enema were left to the discretion of the nurses. Plaintiffs also alleged negligence in the general poor quality of care that was received at the hospital. However, plaintiffs had not presented the requisite expert testimony as to the standard of care and skill required of a reasonably competent hospital. A layperson could not have determined without expert testimony that the patient's rectal problems stemmed from her need of an enema as opposed to the original hemorrhoid surgery.


OUTCOME: The grant of summary judgment in favor of the hospital was affirmed. The denial of plaintiffs' motion to vacate was affirmed.


CORE TERMS: enema, nurse, expert testimony, summary judgment, rectal, bowel, **EXHIBIT**





malpractice, motion to vacate, bowel movement, bleeding, surgery, emergency room, experiencing, discharged, hemorrhoid, layperson, evening, patient, doctor, bath, pain, reasonably competent, genuine issue, skill, genuine issue of material fact, loss of consortium, common knowledge, implementing, obstruction, malpractice

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Civil Procedure > Summary Judgment > Summary Judgment Standard 

HN1  The appellate court reviews de novo a district court's grant of summary judgment. [More Like This Headnote](#)

Civil Procedure > Summary Judgment > Summary Judgment Standard 

HN2  Summary judgment is granted if there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law. Fed. R. Civ. P. 56(c). In reviewing a grant of summary judgment, the court must draw all justifiable inferences in favor of the nonmoving party. [More Like This Headnote](#)

Torts > Malpractice Liability > Healthcare Providers 

HN3  In Kentucky, a medical malpractice plaintiff must prove two things: that the treatment given was below the degree of care and skill expected of a reasonably competent practitioner and that the negligence proximately caused injury or death. The general rule in Kentucky is that malpractice must be established by medical or expert testimony unless the negligence and injurious results are so apparent that laymen with a general knowledge would have no difficulty in recognizing it. [More Like This Headnote](#)

COUNSEL: For DARLENE WHEELER, JAMES WHEELER, Plaintiffs - Appellants: Freeda M. Clark, Clark & Grafton, Louisville, KY.

For BAPTIST HEALTHCARE SYSTEM, INC., Defendant - Appellee: Jonathan Freed, William Robert Long, Jr., Gorman Bradley, Jr., Bradley & Freed, Paducah, KY.

JUDGES: BEFORE: MARTIN, Chief Judge; NORRIS, Circuit Judge; QUIST, District Judge. *

* The Honorable Gordon J. Quist, United States District Judge for the Western District of Michigan, sitting by designation.

OPINION: [*559]

PER CURIAM.

Darlene and James Wheeler appeal the district court's grant of Baptist Healthcare's motion for summary judgment on their claim of medical malpractice and loss of consortium. They also appeal the district court's denial of their motion to vacate the summary judgment order. **[*560]**

I.

On May 19, 1998, Darlene Wheeler, an Illinois resident, began experiencing rectal **[**2]** pain. On May 26, she saw her doctor, Dr. Randy Oliver, who diagnosed her with severe hemorrhoids. Dr. Oliver called Dr. Charles Shields, a surgeon, who told Wheeler that he would perform surgery on her hemorrhoids that evening at Western Baptist Hospital in Paducah, Kentucky. Dr. Shields informed Wheeler that she would be in the hospital for twenty-three hours and that the hospital staff would give her rectal soaks, cleanings, and sitz

baths (shallow baths taken in a seated position). He did not inform her of any effect the surgery might have on her bowels.

Wheeler remained in the hospital until May 31 because she was having urination problems after the surgery. Dr. Shields noted on May 29 that Wheeler would be "discharged home after enemas if she has a good bowel movement and has no problems with voiding after removal of the catheter." She did not have any bowel movements on May 27 or 28, and she began experiencing severe rectal pain on May 29. A nurse who gave her a catheter on May 29 asked Wheeler if she had had a bowel movement that day. Wheeler answered that she might have had a small one. The nurse asked Wheeler if she thought she should be given an enema. Wheeler replied that **[**3]** she did not know but that the nurse should know. Wheeler was not given an enema. Later that afternoon, Wheeler asked the nurses to look in her sitz bath water to determine if any bowel movement was in it because she could not discern whether any loose stool was present in the discolored water. Although Wheeler stated that she did not have any substantial bowel movements on May 29, the daily patient care record for May 29 appears to indicate three stool eliminations during the 7:00 a.m.-to-3:00 p.m. shift. Wheeler also experienced rectal bleeding during the evening of May 29.

Wheeler was released on May 31. After she was home, she continued to experience rectal pain and heavy bleeding. On the morning of June 1, she called Dr. Shields, and he told her that if her symptoms worsened, she should go to the emergency room. She did go to the emergency room at approximately 6:30 that evening. A doctor in the emergency room thought that Wheeler was experiencing bowel obstruction and should be admitted. Wheeler refused to be admitted if she had to return to the same floor where she had been staying, and she was allowed to stay on a different floor of the hospital. Once she was admitted, a nurse **[**4]** gave Wheeler an enema, which proved effective in removing the bowel obstruction. Wheeler was discharged on June 3 but did not resume normal activity for about two months.

On November 9, Wheeler and her husband filed a medical malpractice complaint against the hospital alleging negligence, gross negligence, and loss of consortium. The complaint alleged several specific negligent actions, most of which resulted from inattentive and unresponsive nursing staff. The complaint requested compensatory damages of at least \$ 75,000 as well as punitive damages.

On November 25, Baptist Healthcare served the Wheelers with interrogatories and a request for production, including expert identification. On September 1, the Wheelers identified their experts as Dr. Shields, Wheeler's treating surgeon, and Dr. Oliver, her family doctor, but did not attach any affidavits from them. On October 26, Baptist Healthcare filed a motion for summary judgment, arguing that the Wheelers had presented no proof that it had deviated from accepted medical standards of care. On the same day, Baptist **[*561]** Healthcare also moved to strike the Wheelers' expert witnesses. On November 3, Baptist Healthcare filed its designation **[**5]** of expert witness, Dr. Paulette Adams, and attached Dr. Adams's report letter and curriculum vitae. Dr. Adams stated that the physician's orders "left the decision for implementing the procedure at the discretion of the nurse caring for Mrs. Wheeler. The nurses caring for Mrs. Wheeler documented their assessment of the abdomen and intestinal tract and found no symptoms that might alert them to any pending complications."

The district court granted Baptist Healthcare's summary judgment motion on January 31, 2000, on the ground that the Wheelers had not presented the necessary expert evidence that the hospital was negligent or that any negligence caused her medical problems. On February 10, the Wheelers filed a motion to vacate the order granting summary judgment, which the district court denied on March 20. On April 19, the Wheelers filed a notice of appeal from the denial of their motion to vacate and from the district court's summary judgment decision.

II.

^{HN1} We review de novo a district court's grant of summary judgment. See *Junger v. Daley*, 209 F.3d 481, 484 (6th Cir. 2000). ^{HN2} Summary judgment is granted if there is no genuine issue as to any material fact and the **[**6]** moving party is entitled to a judgment as a matter of law. See Fed. R. Civ. P. 56(c). In reviewing a grant of summary judgment, we "must draw all justifiable inferences in favor of the nonmoving party." *Masson v. New Yorker Magazine, Inc.*, 501 U.S. 496, 520, 115 L. Ed. 2d 447, 111 S. Ct. 2419 (1991).

Because jurisdiction in this case is based on diversity, we apply the substantive law of Kentucky. See *Erie R. Co. v. Tompkins*, 304 U.S. 64, 82 L. Ed. 1188, 58 S. Ct. 817 (1938).

^{HN3} In Kentucky, a medical malpractice plaintiff must prove two things: "that the treatment given was below the degree of care and skill expected of a reasonably competent practitioner and that the negligence proximately caused injury or death." *Reams v. Stutler*, 642 S.W.2d 586, 588 (Ky. 1982). The general rule in Kentucky is that malpractice "must be established by medical or expert testimony unless the negligence and injurious results are so apparent that laymen with a general knowledge would have no difficulty in recognizing it." *Johnson v. Vaughn*, 370 S.W.2d 591 596 (Ky. Ct. App. 1963).

Wheeler argues that although she presented no medical **[**7]** expert evidence, three medical documents ordering an enema for May 29 are sufficient to create a genuine issue of material fact as to negligence. She claims that the hospital was negligent in not following doctor's orders to give her an enema and that no expert testimony is necessary to illustrate the negligence involved. She presented the physician's orders for routine post-hemorrhoidectomy care, which included an enema on the third post-operative day; a daily physician's orders sheet that noted to discharge her on May 29 "after enemas today if good BM"; and Dr. Shields's discharge summary, dated May 29, which stated, "Today, she will be discharged home after enemas if she has a good bowel movement." Wheeler argues that not following these orders constitutes negligence within the scope of common knowledge of laypersons.

Kentucky courts have identified several cases of negligence that were within the scope of common knowledge of laypersons and thus did not require expert testimony. See, e.g., *City of Somerset v. Hart*, 549 S.W.2d 814 (Ky. 1977) (scalpel blade left in patient's bladder); *Laws v. Harter*, 534 S.W.2d 449 (Ky. Ct. App. 1976) (sponge left **[**8]** in abdomen); *Jewish Hospital Ass'n v. Lewis*, 442 S.W.2d 299 (Ky. Ct. App. 1969) (excessive bleeding after catheterization); *Meiman v. Rehab. Ctr., Inc.*, 444 S.W.2d 78 (Ky. Ct. App. 1969) (bone broken during physical therapy); *Jarboe v. Harting*, 397 S.W.2d 775 (Ky. Ct. App. 1965) (misdiagnosis of pregnancy as uterine tumor); *Neal v. Wilmoth*, 342 S.W.2d 701 (Ky. Ct. App. 1961) (dentist's losing balance, falling onto patient, and jamming drill into patient's tongue and soft palate); *Butts v. Watts*, 290 S.W.2d 777 (Ky. Ct. App. 1956) (fragment of extracted tooth left in socket). The Kentucky Supreme Court has noted the classic example of a situation "where lay testimony is sufficient to make a submissible jury issue" -- amputating the wrong leg. *Mahaffey v. McMahon*, 630 S.W.2d 68 (Ky. 1982).

Rather than being analogous to amputation of an incorrect limb, Wheeler's case is more in line with Kentucky cases finding expert testimony to be necessary, many of which involve the necessity of performing some medical procedure. See, e.g., *Turner v. Reynolds*, 559 S.W.2d 740 (Ky. Ct. App. 1977) **[**9]** (necessity of head x-rays after being stabbed in head); *Stokes v. Haynes*, 428 S.W.2d 227 (Ky. Ct. App. 1968) (necessity of hospitalization of woman threatened with miscarriage); see also *Maggard v. McKelvey*, 627 S.W.2d 44 (Ky. Ct. App. 1981) (failed performance of vasectomy). In addition, we have also reviewed a medical malpractice claim under Kentucky law and concluded that expert testimony was necessary on the issue of whether a hospital was negligent in failing to diagnose pneumonia and Legionnaires' disease. See *Vance v. United States*, 90 F.3d 1145 (6th Cir. 1996).

In the present case, the Wheelers have presented no evidence to counter Baptist Healthcare's expert affidavit that the physician's orders for the enema were left to the discretion of the nurses. Without showing that physician's orders must always be followed to the letter or that nurses have no discretion in implementing physician's orders, the Wheelers have not created a genuine issue of material fact sufficient to prevent summary judgment. Wheeler also alleges negligence in the general poor quality of care she received at the hospital. While this Court may sympathize **[**10]** with her admittedly grim experience, the Wheelers have not presented the requisite expert testimony as to the standard of care and skill required of a reasonably competent hospital.

Because the Wheelers have not created a genuine issue of fact as to negligence, we need not reach the causation step of the malpractice analysis. Even assuming the Wheelers had shown negligence, they have not presented expert testimony to show that the nurses' failure to give Wheeler an enema caused her discomfort and rectal bleeding. A layperson could not determine without expert testimony that Wheeler's rectal problems stemmed from her need of an enema as opposed to the original hemorrhoid surgery.

III.

For the foregoing reasons, we AFFIRM the district court's grant of summary judgment in favor of Baptist Healthcare. We likewise AFFIRM the district court's denial of the Wheelers' motion to vacate.

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